

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group IV, claims 5, 9-14, 18 and 22-24, in the reply filed on 27 March 2011 is acknowledged. The traversal is on the ground(s) that the claims were not determined under the PCT phase to have failed unity of invention (page 7 of the Remarks). Applicants argue that each claim is dependent either on an embodiment unique to the MON88017 event, a particular segment of DNA that is uniquely present in the MON88017 event genome, or with reference to method claims, the detection of the presence of a segment of polynucleotide unique to the MON88017 event genome as set forth in SEQ ID NO: 1 and/or SEQ ID NO: 2 when detected in or present in corn genomic DNA corresponding to corn event MON88017 as to form a single genomic DNA (page 8 of the Remarks). This is not found persuasive because 37 CFR 1.499 states that claims can be reviewed for Lack of Unity at the national stage, there is no requirement that Lack of Unity be expressed during the PCT stage or that there is a bar against a finding of Lack of Unity at the national stage. As to unity of invention, the invention of instant Claim 4, for example, does not require the use of a corn plant comprising MON88017 event *per se* nor does said claim require the use of any part thereof, only that one looks for an amplicon comprising SEQ ID NO: 1 or SEQ ID NO: 2.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-4, 6-8, 15-17 and 19-21 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 March 2011.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Claim Objections***

4. Claims 5, 9, 10, 13 and 23 are objected to because of the following informalities:

Claim 5 is objected to for being dependent from a non-elected claim.

Claim 9 is objected to for being unclear because "is corn event MON88017" appears to refer to the original transformation event, it appears that the claim should recited -- comprises corn event MON88017 --.

Claims 10 and 13 lack an article of language and should start with -- A --.

Claim 23 is objected to for failing to comply with 37 CFR 1.75(c). For the purposes of this Office action said claim is read as being dependent from claim 22. Failure to correct this issue will be considered non-responsive to this Office Action.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 10, 11-13, 18 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 5, it is unclear if the claimed "transformed maize plant" comprises corn event MON88017, because SEQ ID NO: 1 and SEQ ID NO: 2 are 20mers and the claim only requires one or the other, hence the metes and bounds of the claim are unclear.

Claim 10 is indefinite because it is unclear what has been deposited. At page 3, paragraph 10, Applicants refer to a corn plant designated MON88017. Hence, the metes and bounds of the claim are unclear.

At claim 11, corn plant MON88017 lacks proper antecedent bases in claim 10 upon which it depends. Claims 12 and 13 depend from claim 11, and are thus similarly indefinite.

At claim 18, line 2, "the corn event MON88017" lacks proper antecedent basis within the claims. In addition SEQ ID NO: 1 or SEQ ID NO: 2 does not define the metes and bounds of corn event MON88017.

At claims 22 and 23, SEQ ID NO: 1 or SEQ ID NO: 2 does not define the metes and bounds of corn event MON88017, and "a detectable amount of a corn event MON88017" does not define the metes and bounds of the claimed invention.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to what conditions the deposit was made or as to the public availability.

(a) If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

(b) If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent in accordance with 37 CFR § 1.808(a)(2);
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

9. Claims 5, 13, 14, 18, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a corn plant comprising corn event MON88017 and compositions comprising corn event MON88017, does not reasonably provide enablement for a corn plant comprising SEQ ID NO: 1 or 2 or compositions made therefrom. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim a corn/maize plant comprising SEQ ID NO: 1 or SEQ ID NO: 2 which are 20mer DNA sequences usable to produce an amplicon diagnostic of corn event MON88017.

Applicants teach corn/maize plants comprising corn event MON88017.

Applicants do not teach how to make and use corn/maize plant comprising only SEQ ID NO: 1 or SEQ ID NO: 2 because said sequences are a subset of corn event MON88017 which is a random and unpredictable event that would not be reproducible. Hence, the claims would require undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use as broadly claimed.

### ***Conclusion***

10. Claim 24 is allowed.
11. Claim 9 is objected to.
12. Claims 5, 10-14, 18, 22 and 23 are rejected.
13. The claims are free of the prior art which does not teach corn event MON88017, or a corn plant comprising SEQ ID NO: 1 or SEQ ID NO: 2.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
3 June 2011